

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

SANOFI-AVENTIS, SANOFI-  
AVENTIS U.S. LLC,

Plaintiffs,

v.

SANDOZ, INC.,

Defendant.

Civil Action No. 07-1605 (WJM)

**OPINION**

**FALK, U.S.M.J.**

Before the Court is an application by Plaintiffs Sanofi-Aventis and Sanofi-Aventis U.S. LLC (collectively “Plaintiffs” or “Sanofi”) to compel the deposition of a witness from Defendant Sandoz, Inc. on activities performed by Lek Pharmaceuticals d.d. (“Lek”), an “affiliate” of Sandoz, Inc., pursuant to Federal Rule of Civil Procedure 30(b)(6). Defendant Sandoz, Inc. opposes. For the reasons set forth below, Plaintiffs’ request is **granted**.

**I. Background**

**A. Procedural History**

Sanofi-Aventis is the owner of United States Patent No. 6,514,531 (“the ‘531 patent”). The ‘531 patent covers a pharmaceutical controlled-release dosage form adapted to release zolpidem, which is sold by Sanofi-Aventis U.S. LLC as Ambien CR®. The Food and Drug Administration (“FDA”) approved Ambien CR® for insomnia treatment on September 2, 2005.

Defendant Sandoz filed an abbreviated new drug application (“ANDA”) with the FDA pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355(j)(1), in which it sought approval to manufacture generic zolpidem tartrate extended-release tablets prior to the expiration of

the ‘531 patent. As part of its ANDA, Sandoz asserts that its generic does not infringe on the ‘531 patent or, alternatively, that the ‘531 patent is invalid. Id. § 355(j)(2)(A)(vii). Sandoz had Lek, a Slovenian pharmaceutical company, develop and manufacture its ANDA product. Lek is a wholly-owned subsidiary of Novartis, the parent company of Sandoz. Thus, Sandoz and Lek may be referred to as “sister” companies.

Sanofi filed suit against Sandoz, Inc. under 35 U.S.C. § 271(e)(2) for infringing on its ‘531 patent. That suit was then consolidated with similar cases under the above-captioned docket number [CM/ECF No. 9]. After the close of fact discovery, the FDA changed its criteria for evaluating the bioequivalency of generic copies of zolpidem tartrate controlled release tablets. See Draft Guidances for Industry Describing Product-Specific Bioequivalency Recommendations; Availability, 74 Fed. Reg. 62,793 (Dec. 1, 2009) (announcing availability of new bioequivalency guidelines for “zolpidem”).<sup>1</sup> Soon thereafter, the FDA informed Sandoz that certain aspects of its ANDA did not meet the revised bioequivalency parameters. Sandoz then had Lek manufacture new sample generic tablets for supplemental testing under the new bioequivalency standards. At Plaintiffs’ request, fact discovery was re-opened so that Sanofi could investigate the new samples made by Lek.

### **B. The Discovery Dispute**

As part of its fact discovery, Sanofi noticed a 30(b)(6) deposition of Defendant Sandoz, Inc. on a range of nineteen (19) topics related to the supplemental bioequivalency testing of its new ANDA product. Sandoz objected to all but three (3) discrete topics primarily because it claimed to have no witness to designate with knowledge of matters

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<sup>1</sup> Defendants Mutual Pharmaceutical Company Inc., United Research Laboratories, Inc., and Barr Laboratories, Inc. withdrew their ANDA applications as a result of the new guidelines and were voluntarily dismissed without prejudice from this consolidated action, leaving Sandoz as the sole Defendant [CM/ECF Nos. 73, 76].

performed by a “third-party.” After engaging new counsel, Sandoz instead offered to provide two Lek witnesses in a 30(b)(1) capacity to cover twelve (12) of the noticed topics. Without waiving its position that it was entitled to 30(b)(6) testimony on all topics, Sanofi held a 30(b)(1) deposition of one Lek scientist. The witness testified on four (4) topics but apparently was not fully responsive to all questions due to a lack of personal knowledge. After further negotiations, Sandoz changed its position and offered to provide one 30(b)(6) witness on all information known to Sandoz—not Lek—on sixteen (16) of the nineteen (19) topics. Sanofi now seeks one fully-responsive 30(b)(6) witness on all topics.

Since the outset of this evolving dispute, Sanofi has urged that the knowledge required of a 30(b)(6) witness extends beyond the information in the current possession of its principal. Indeed, it argues that the rule itself provides for all information “known or reasonably available to the organization.” Fed. R. Civ. P. 30(b)(6). Sanofi points out that Sandoz has regularly called on Lek for information in response to FDA requests and has even produced Lek witnesses in this case when it was advantageous to do so. Sanofi further argues that the parties agreed over two years ago that Sandoz would provide discovery from Lek “as though it [were] a party.”

Sandoz opposes principally on the ground that a 30(b)(6) deponent must have “control” over a corporate affiliate to establish that information in its possession is reasonably available. Sandoz states that it does not own Lek, and its ability to occasionally obtain information from Lek does not in any way alter its status as a distinct legal entity. It also disputes the accuracy of the agreement reached between the parties. Initially, Sandoz took the position that it only agreed to produce “certain” documents and deponents from Lek “as an accommodation to Sanofi.” It later conceded that Sandoz agreed that “it would not

withhold Lek documents on the grounds that Lek is a third-party.”

## **II. Discussion**

### **A. Rule 30(b)(6) of the Federal Rules of Civil Procedure**

Rule 30(b)(6) permits a party to name a “public or private corporation . . . or other entity” as a deponent so long as the notice describes the matters for examination “with reasonable particularity.” To the extent the notice describes matters that are relevant under the broad scope of discovery, Fed. R. Civ. P. 26(b)(1), the entity must designate one or more individuals to testify on its behalf. Fed. R. Civ. P. 30(b)(6). As a representative of the named deponent, the testimony of a 30(b)(6) witness is binding on the entity. Harris v. New Jersey, 259 F.R.D. 89, 92 (D.N.J. 2007); see also Resolution Trust Corp. v. S. Union Co., 985 F.2d 196, 197 (5th Cir. 1993) (“[T]he corporation appears vicariously through that agent.”).

Although the individuals selected to testify need not have personal knowledge, Rule 30(b)(6) imposes an obligation on the entity to prepare the witnesses so that they can answer all noticed topics fully, accurately, and non-evasively. See Harris, 259 F.R.D. at 92 (quoting Mitsui & Co. v. P.R. Water Res. Auth., 93 F.R.D. 62, 67 (D.P.R. 1981)); see also Black Horse Lane Assoc., L.P. v. Dow Chem. Corp., 228 F.3d 275, 304 (3d Cir. 2000). The scope of questioning at a 30(b)(6) deposition is coextensive with Rule 26(b)(1), but the witnesses must be prepared to testify to at least those topics identified in the notice. See Bracco Diagnostics, Inc. v. Amersham Health, Inc., No. 03-6025, 2005 Dist. LEXIS 26854, at \*5 (D.N.J. Nov. 4, 2005). This affirmative duty extends only to information “known or reasonably available to the organization.” Fed. R. Civ. P. 30(b)(6); 8A Charles Alan Wright et al., Federal Practice and Procedure § 2103, at 457 (3d ed. 2010). Determining if certain information is “known or reasonably available” to an entity requires a fact-specific analysis.

See Coryn Group II, LLC v. O.C. Seacrets, Inc., 265 F.R.D. 235, 239 (D. Md. 2010).

## **B. Analysis**

In its submissions, Sandoz takes the position that information on the activities performed by Lek, its sister company, is not currently “known” to any employee at Sandoz. This is apparently undisputed by Sanofi. The Court therefore turns to the question of whether this information is “reasonably available” to Sandoz for purposes of Rule 30(b)(6).

### **i. Information from Related Entities**

As an initial matter, the Court must determine whether knowledge from a corporate affiliate falls within the scope of information a 30(b)(6) deponent must investigate as part of its preparation obligations. In other words, under what circumstances is information held by a related entity something that can be “reasonably available” to a corporation named in a 30(b)(6) notice.

The “or reasonably available” language of Rule 30(b)(6) clearly contemplates information beyond the present domain of the noticed entity. For example, a number of courts stress that a corporation must educate a 30(b)(6) designee, whether from “documents, past employees, or other sources,” in order to obtain responsive information. E.g., Brazos River Auth. v. GE Ionics, Inc., 469 F.3d 416, 433 (5th Cir. 2006) (quoting United States v. Taylor, 166 F.R.D. 356, 361 (M.D.N.C. 1996)); Costa v. Cnty. of Burlington, 254 F.R.D. 187, 189 (D.N.J. 2008) (same); Harris, 259 F.R.D. at 92 (same). Relatively few cases, however, specify whether a corporation must familiarize itself on activities performed by a distinct, but related entity. The limited amount of authority that has directly addressed whether a 30(b)(6) deponent must prepare its witness with knowledge from a related entity demonstrates that the “or reasonably available” language of Rule 30(b)(6) can extend to

information held by corporate affiliates. See Ethypharm, S.A. Fr. v. Abbott Labs., 271 F.R.D. 82, 95-96 (D. Del. 2010); Coryn Group II, LLC v. O.C. Seacrets, Inc., 265 F.R.D. 235, 239 (D. Md. 2010); In re Classicstar Mare Lease Litig., MDL No. 1877, 2009 WL 1313311, at \*2 (E.D. Ky. May 12, 2009); Murphy v. Kmart Corp., 255 F.R.D. 497, 509 (D.S.D. 2009); S.C. Johnson & Son, Inc. v. Dial Corp., No. 08 C 4696, 2008 WL 4223659, at \*2 (N.D. Ill. Sept. 10, 2008); Honda Lease Trust v. Middlesex Mut. Assurance Co., No. 3:05CV1426, 2008 WL 3285242, at \*3 (D. Conn. Aug. 7, 2008); Twentieth Century Fox Film Corp. v. Marvel Enter., Inc., No. 01 Civ 3016, 2002 WL 1835439, at \*4 (S.D.N.Y. Aug. 8, 2002).

In Twentieth Century Fox, the court required the entity subpoenaed under 30(b)(6) to produce a witness prepared to testify with knowledge of its direct subsidiary. 2002 WL 1835439, at \*5. To reach this conclusion, the court used the “control” standard of Rule 34(a) as a guideline to determine whether Rule 30(b)(6) encompasses the knowledge of corporate affiliates. Id. at \*4. Courts within the Third Circuit have broadly interpreted “control” in the context of document production. See, e.g., Camden Iron & Metal, Inc. v. Marubeni Am. Corp., 138 F.R.D. 438, 441 (D.N.J. 1991) (“Control is defined as the legal right, authority or ability to obtain documents upon demand.” (citations omitted)). In Gerling Int’l Ins. Co. v. Comm’r of Internal Revenue, the Third Circuit established that “control” is present for Rule 34(a) when the litigating corporation either can secure documents from the related entity to meet its business needs or acted with it in the transaction that gave rise to the suit. 839 F.2d 131, 140-41 (3d Cir. 1988) (emphasis added); see also Camden Iron, 138 F.R.D. at 443. Gerling established that a corporation can be required to produce documents from a sister company, such as Lek, when it acted with its sister company in the transaction at issue. See, e.g., Davis v. Gamesa Tech. Corp., 2009 WL 3473391, at \*5-\*6 (E.D. Pa. Oct. 29, 2009).

Other courts since Twentieth Century Fox have held that knowledge from entities beyond a deponent's direct subsidiary can also be "reasonably available" under Rule 30(b)(6). For instance, they have required a 30(b)(6) designee to obtain information from a subsidiary with "eight degrees of ownership separation" between it and the parent, S.C. Johnson & Son, 2008 WL 4223659, at \*2, "affiliates" of the corporate entity named in notice, Coryn Group, 265 F.R.D. at 239, and, most importantly, the "parent" and "sister" company of 30(b)(6) deponent, Murphy, 255 F.R.D. at 509. In all of these cases, the litigating corporation had either the legal or practical ability to obtain information from its corporate affiliate. The only case where a court declined to find information from a related entity "reasonably available" involved a subpoena that sought information on matters in which the named deponent was entirely uninvolved. See In re Ski Train Fire of Nov. 11, 2000 Kaprun, Austria, 64 Fed. R. Serv. 3d 594, 602 (S.D.N.Y. 2006). In other words, the company named in the 30(b)(6) notice did not act with its affiliate in the transaction that gave rise to the lawsuit. Of course, Ski Train was not a Hatch-Waxman patent case.

In short, knowledge from corporate affiliates can be "reasonably available" to a 30(b)(6) deponent in certain instances. Direct, legal control over the related entity is not required. However, corporate form without more does not end the inquiry. The availability of information in the possession of a related company turns on the facts of each case, in particular as they relate the "control" standard of Rule 34(a).

## **ii. Information From Lek Is Reasonably Available to Sandoz**

### **a. Sandoz Can Procure Documents from Lek As Needed**

The control test articulated by the Third Circuit in Gerling International "focuses on the relationship between the two entities." 839 F.2d at 140. In this case, Sandoz and Lek are

corporate sisters. However, Plaintiffs provide evidence of an even closer relationship between Sandoz and Lek. For example, Sanofi points out that Lek's website projects itself to the general public as a "Sandoz company." The corporate logo of Sandoz is prominently displayed in several locations throughout its homepage. Plaintiffs also cite a number of representations made by Sandoz in submissions to the FDA that portray its relationship with Lek. In one of its FDA submissions, Sandoz describes Lek as "an affiliate company **of Sandoz** [that] performs activities **at the request of Sandoz**." Another characterizes the foreign facility as "**our** Lek Pharmaceuticals d.d. (**Sandoz**) plant located [in] Slovenia." Lek even stated in a letter to the FDA to forward all correspondence to its "**primary Agent: Sandoz Services, Inc. c/o Sandoz, Inc.**"

Sandoz contends that these excerpts only establish that the two companies have a common buyer-supplier relationship. The facts indicate it is far more. Sandoz lists several Lek witnesses as "Sandoz employee[s]" in its privilege log. Sandoz has arranged for the production of Lek employees for consultation with its own experts throughout this case as the need arose. In fact, it acknowledges that it has produced documents and witnesses from Lek during the course of this case as an "accommodation" to Sanofi. As for document production specifically, Sandoz accepts that it reached an arrangement with Sanofi over two years ago under which "**it [Sandoz] would not withhold Lek documents on the grounds that Lek is a third-party.**" These ties show a relationship that goes beyond conventional business dealings and at the very least establish that Sandoz can secure documents from Lek in the ordinary course of business.

#### **b. Sandoz and Lek Acted Together in the Transaction at Issue**

Most importantly, it is beyond dispute that sister corporations Sandoz and Lek acted



together in seeking FDA approval of generic Ambien CR®. Sandoz's ANDA filing directly triggered this patent action, pursuant to the choreographed Hatch-Waxman framework. See 35 U.S.C. § 271(e)(2); Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990). As previously noted, Lek developed and manufactured the generic product at issue in this case at the behest of Sandoz. The work performed by Lek is central to the claim of infringement here. As such, "any question regarding infringement will necessarily reference acts [the corporate affiliate] performed." Afros S.P.A. v. Krauss-Maffei Corp., 113 F.R.D. 127, 132 (D. Del. 1986).

Sandoz cannot use its foreign affiliation with Lek as both a sword and a shield. Sandoz has relied on Lek in its submissions made to the FDA in connection with its ANDA. Information gathered from Lek's supplemental testing will be provided, much like the initial testing, to the FDA for further consideration under the revised guidelines. Sandoz now attempts to block discovery of these very activities because it claims this information is not "reasonably available." Similarly, Sandoz asserts privilege over communications held with Lek scientists because they were held with "Sandoz employee[s]." Yet it now argues that Lek is an entirely distinct legal entity for purposes of Rule 30(b)(6). Sandoz cannot have it both ways. Common sense and traditional notions of justice demand that Sandoz is required to provide discovery about Lek in this litigation as it would voluntarily in the ANDA process.

The relationship between Sandoz and Lek squarely meets the level of "control" required for a sister corporation under Gerling International. In fact, Magistrate Judge Patty Shwartz recently held in an unrelated Hatch-Waxman case that the relationship between Sandoz and Lek satisfies the requisite level of control, as that term is used under Rule 34(a). See Merck & Co. v. Sandoz, Inc., No. 10-cv-1625, CM/ECF Entry No. 62 (D.N.J. Nov. 23,

2010). The case involved a document request served on party defendant Sandoz, Inc. that sought documents from its two foreign sister corporations, Lek and Sandoz GmbH. Id. at 2. Sandoz similarly argued that its foreign affiliates were distinct legal entities and that it only had a common “buyer-supplier arrangement” with each of them. Id. at 4. Judge Shwartz concluded that Sandoz must produce documents from Lek and Sandoz GmbH pursuant to Rule 34(a) largely because they acted together in seeking approval of the generic. Id. at 11-12. In particular, Judge Shwartz noted the following:

[T]here is no doubt that [Sandoz and its two sister companies] had a free flow of exchange of information in furtherance of the documents giving rise to this suit. They had regular contact during the course of the transaction, and the foreign sisters provided critical assistance to Sandoz, Inc.’s ability to make its application, both in terms of the contributions to the modules, its direct communications with the FDA in furtherance of that application, and the important role that Lek would play in manufacturing and testing the ANDA product.

Id. at 12. Needless to say, the Undersigned fully agrees with the impeccable reasoning in the Merck case.

The relationship between Sandoz and Lek clearly meets the “control” test for sister corporations under governing case law. See Gerling Int’l, 839 F.2d at 140. This fact is dispositive to the 30(b)(6) analysis for knowledge from a sister corporation. See Murphy, 255 F.R.D. at 509. Thus, information from Lek on its supplemental testing is “reasonably available” to Sandoz for purposes of Rule 30(b)(6).

### **c. Practical Considerations in ANDA Patent Cases**

The Court unscientifically observes an apparent increase in similar disputes arising in Hatch-Waxman patent cases. More specifically, a party will rely on a foreign corporate affiliate for some aspect of its ANDA submission and then attempt to limit (or in some cases make difficult) discovery of the foreign affiliate in the ensuing patent litigation.

This practice is impractical, unfair and will not be sanctioned by this Magistrate Judge. ANDA cases are a specialized form of patent litigation, often involving high stakes and contentious litigation. Indeed, this district has adopted specialized local rules for cases arising under the Hatch-Waxman Act. See L. Pat. R. 3.6 (codified in L. Civ. R. 9.3). When an ANDA applicant relies on a foreign affiliate to seek FDA approval in the United States, it should be prepared to produce discovery from the affiliate in any patent litigation arising from that submission. If the FDA sought such information, one would expect the applicant to quickly obtain responsive material—at the risk compromising the approval of its ANDA. If a party in the patent litigation regarding the ANDA, which is expressly contemplated by the statute, seeks the same information, the applicant should facilitate it in the same way it would for the FDA. If not, it should be at the risk of its position in the litigation. The Court and parties should not be burdened with repetitive discovery disputes on this subject.

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Accordingly, Sandoz is required to produce one or more individuals to testify on its behalf with knowledge of the activities performed by Lek in response to the 30(b)(6) notice.

### **III. Conclusion**

For the reasons stated above, Plaintiffs' application to compel the deposition of a 30(b)(6) witness from Defendant Sandoz, Inc. is **granted**. A separate Order accompanies this opinion.

/s/ Mark Falk  
**MARK FALK**  
**United States Magistrate Judge**

Dated: January 28, 2011